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AUG 25 2008

# 510(k) Summary Pursuant to 21 CFR 807.92

1. Submitted By: Pioneer Surgical Technology
   375 River Park Circle
   Marquette, MI 49855

2. Contact: Jon Gilbert
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   Marquette, MI 49855
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3. Product: Pioneer Surgical NanOss BVF-E
   CFR Section 880.3045 Resorbable Calcium
   Salt Bone Void Filler Device
   Class II (special controls)
   Product Code: MQV

4. Common/Trade Name:

   Filler, Bone Void, Calcium Compound
   Pioneer NanOss BVF-E

Description:
***Pioneer Surgical Technology NanOss BVF-E*** is a porous calcium phosphate material mixed with a gelatin based carrier. The product is an osteoconductive scaffold mixed with a gelatin carrier for use in repairing bony defects in spinal and general orthopedic indications.

The product is supplied sterile for single use in various configurations, as pre-mixed granules, or in separate containers to be combined by the user or as pre-molded strips and forms. A commercially available dispensing syringe and a mixing spatula are included in the package.

Intended Use/Indication:
NanOss BVF-E is intended for bony voids or gaps that are not intrinsic to the stability of bony structure. The product is indicated to be gently packed into bony voids or gaps in the skeletal system (extremities, pelvis). These defects may be surgically created osseous defects or defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced by the growth of new bone during the healing process.

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Technological Characteristics:
NanOss BVF is a macroporous ceramic granule composed of greater than 95% nanocrystalline hydroxyapatite. The calcium phosphate granules are presented as ground particles. The macroporous structure of the NanOss provides a resorbable osteoconductive scaffold.

The gelatin based carrier is presented as ground freeze-dried particles. The combined product forms a cohesive and adhesive material upon rehydration with surgical fluids, e.g. saline or blood.

Performance Testing:
E-Matrix NanOss BVF and/or components have undergone non-clinical testing, including chemical, physical, component biocompatibility, and handling characteristics. Testing provides reasonable assurance of safety and effectiveness for its intended use and supports a determination of substantial equivalence to the predicate devices.

Substantial Equivalence:
Pioneer Surgical NanOss BVF-E is comparable to several Bone Void Filler devices already on the market. One of the predicate devices (NanOss Bone Void Filler) is a major component of the new product. Predicate devices are similar in characteristics, which may include indications, ceramic materials, porcine gelatin carrier, porous structure, and presentation.

Devices to Which Substantial Equivalence is Claimed:

K032288– Vitoss Scaffold Foam Bone Graft Material

K050025 – Angstrom Medica, Inc. NanOss Bone Void Filler

K043421 – RTI Opteform

K060728 – NovaBone Putty – Bioactive Synthetic Graft

Conclusions:
The comparisons and testing conducted on Pioneer Surgical NanOss BVF-E demonstrate that the device is substantially equivalent to other bone void fillers currently in commercial distribution. Additionally, it meets all of the requirements of the FDA special controls guidance (*Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA*).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Pioneer Surgical Technology
% Mr. Jonathan Gilbert
VP, Regulatory and Clinical Affairs
375 River Park Circle
Marquette, Michigan 49855

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Re: K081558
Trade/Device Name: Pioneer Surgical NanOss BVF-E
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: May 30, 2008
Received: June 30, 2008

Dear Mr. Gilbert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use Statement

510(k) Number: K081558

Device Name: Pioneer Surgical NanOss BVF-E

Indications for Use: NanOss BVF-E is intended for bony voids or gaps that are not intrinsic to the stability of bony structure. The product is indicated to be gently packed into bony voids or gaps in the skeletal system (extremities, pelvis). These defects may be surgically created osseous defects or defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced by the growth of new bone during the healing process.

Prescription Use X or Over-the-counter use _____
(per CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K081558